



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 26, 2013, from 8 a.m. to 5 p.m.

Location: Holiday Inn, Ballroom, 2 Montgomery Village Ave., Gaithersburg, MD 20879. The hotel phone number is 301-948-8900.

Contact Person: Avena Russell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1535, Silver Spring, MD 20993-0002, [Avena.Russell@fda.hhs.gov](mailto:Avena.Russell@fda.hhs.gov), 301-796-3805, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice.

Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On June 26, 2013, the committee will discuss and make recommendations regarding the possible reclassification of blood lancet devices. The committee will discuss whether new scientific data are sufficient to support the reasonable assurance of safety and effectiveness to develop special controls that support regulation of blood lancets from class I to class II and class III. The four subsets of blood lancets have been identified with the following indications for use:

- Blood lancet with an integral sharps injury prevention feature is for single use only, disposable blood lancet with a blade attached to a solid base which includes an integral sharps injury prevention feature that allows the device to be used once and then renders it inoperable and incapable of further use and which is used to puncture the skin to obtain a drop of blood for diagnostic purposes;
- Blood lancet without an integral sharps injury prevention feature is for single use only, disposable blood lancet with a blade attached to a solid base which is used to puncture the skin to obtain a drop of blood for diagnostic purposes;
- Blood lancet for single patient use only is a multiple use capable blood lancet with a single use blade inserted into a solid, reusable base which is used only for a single patient to puncture the skin to obtain a drop of blood for diagnostic purposes; and

- Multiple use blood lancet for multiple patient use is a multiple use capable blood lancet with a single use blade inserted into a solid, reusable base which is used for multiple patients to puncture the skin to obtain a drop of blood for diagnostic purposes.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before June 7, 2013. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before June 6, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by June 10, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Committee Management Staff, at 301-796-5966 or [AnnMarie.Williams@fda.hhs.gov](mailto:AnnMarie.Williams@fda.hhs.gov) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 17, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.